AMENDMENTS

In the specification:

On page 1, line 3, after the title, insert the following:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 08/939,874, filed on September 29, 1997, now U.S. Patent No. _____, which is a continuation-in-part of U.S. Patent Application Serial No. 08/751,888, filed on November 18, 1996, now abandoned, and a continuation-in-part of U.S. Patent Application Serial No. 08/376,701, filed on January 23, 1995, now U.S. Patent No. 5,795,587, issued August 18, 1998, the disclosures of each of which are hereby incorporated herein by reference.--.

In the claims:

Please cancel claims 1-45 without prejudice or disclaimer.

Please add new claims 46-136 as follows:

46. (New) A drug/lipid/polycationic polypeptide salt complex comprising ~~a drug,~~ at least one lipid species, and ~~at~~ least one polycationic polypeptide salt, wherein the complex ~~has~~ a net neutral or a net negative charge.

47. (New) The complex of claim 46, wherein the complex has a net neutral charge.

48. (New) The complex of claim 46, wherein the complex has a net negative charge.

49. (New) The complex of claim 46 wherein, in ~~the polycationic polypeptide~~ salt, arginine residues constitute at ~~least~~ about 30 % of the amino acid residues, and lysine residues constitute ~~less~~ than about 5 % of the amino acid residues of the polypeptide.

50. (New) The complex of claim 46, wherein the complex comprises a positively charged surface.

51. (New) A nucleic acid/lipid/polycationic polypeptide complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide, wherein the complex has a net neutral or net negative charge, and wherein, in the polycationic polypeptide, arginine residues constitute about 65 to 75 % of the amino acid residues, and lysine residues constitute about 0 to 3% of the amino acid residues of the polypeptide.

52. (New) The complex of claim 46, wherein the polycationic polypeptide salt is a sulfate salt.

53. (New) The complex of claim 46, wherein the polypeptide salt comprises an ion having two negative charges.

54. (New) The complex of claim 46, wherein the polycationic polypeptide salt is a protamine sulfate.

55. (New) The complex of claim 46, wherein the drug is a nucleic acid.

56. (New) The complex of claim 55, wherein the nucleic acid comprises an E1A gene.

57. (New) The complex of claim 46, wherein the lipid is a cationic lipid.

58. (New) The complex of claim 46, wherein the lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

59. (New) The complex of claim 46, wherein the polypeptide is from about 20 to about 100 amino acids in length.

60. (New) The complex of claim 46, wherein the complex further comprises a neutral phospholipid species.

61. (New) The complex of claim 55, wherein the ratio of the nucleic acid:lipid:polycationic polypeptide salt is about 1 µg/0.1 nmol/0.01 µg to about 1 µg/200 nmol/100 µg.

62. (New) The complex of claim 46, wherein the complex has a diameter of less than about 400 nm.

63. (New) The complex of claim 46, wherein the complex is shielded.

64. (New) The complex of claim 46, further comprising a compound comprising polyethylene glycol moieties.

65. (New) The complex of claim 50, wherein the complex is shielded.

66. (New) The complex of claim 65, wherein the complex comprises a compound comprising polyethylene glycol moieties.

67. (New) The complex of claim 46, further comprising a lipophilic surfactant.

68. (New) A method for producing a drug/lipid/polycationic polypeptide salt complex of claim 46, the method comprising combining the drug, the lipid and the polycationic polypeptide salt to form the complex.

69. (New) The method of claim 68, wherein the drug, lipid and polycationic polypeptide salt are mixed in a ratio of about 1 μg/0.1 nmol/0.01 μg to 1 μg/200 nmol/100 μg.

70. (New) The method of claim 68, wherein the lipid is a cationic lipid.

71. (New) The method of claim 70, wherein the cationic lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

72. (New) The method of claim 68, wherein the drug is a nucleic acid.

73. (New) The method of claim 69, wherein the polycationic polypeptide salt is a protamine sulfate.

74. (New) A method for delivering drug to cells comprising contacting the cells with the complex of claim 46.

75. (New) The method of claim 74, wherein the cells are contacted with the complex *in vivo*, the method comprising administering the complex to an animal or human in an amount effective to deliver the drug into the cells of the animal or the human.

76. (New) The method of claim 74, wherein the drug comprises a nucleic acid, the lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol), and the polycationic polypeptide salt is a protamine sulfate.

77. (New) A drug/lipid/polycationic polypeptide salt complex comprising a drug, at least one lipid species, and at least one polycationic polypeptide salt, wherein the complex further comprises a targeting factor.

78. (New) The complex of claim 77, comprising a drug, at least one lipid species, and at least one polycationic polypeptide salt in a ratio such that the complex has a positive charge excess of lipid and polycationic polypeptide to drug.

79. (New) The complex of claim 77, wherein the complex has a net neutral or net negative charge.

80. (New) The complex of claim 77 wherein, in the polycationic polypeptide salt, arginine residues constitute at least about 30 % of the amino acid residues, and lysine residues constitute less than about 5 % of the amino acid residues of the polypeptide.

81. (New) A nucleic acid/lipid/polycationic polypeptide complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide, wherein, in the polycationic polypeptide, arginine residues constitute about 65 to 75 % of the amino acid residues, and lysine residues constitute about 0 to 3% of the amino acid residues of the polypeptide, wherein the complex further comprises a targeting factor.

82. (New) The complex of claim 81, wherein the complex has a net positive charge.

83. (New) The complex of claim 81, wherein the complex has a net neutral or net negative charge.

84. (New) The complex of claim 77, wherein the polycationic polypeptide ~~salt is a~~ sulfate salt.

85. (New) The complex of claim 77, wherein the polypeptide salt comprises an ion having two negative charges.

86. (New) The complex of claim 77, wherein the polycationic polypeptide salt is a protamine sulfate.

87. (New) The complex of claim 77, wherein the drug is a nucleic acid.

88. (New) The complex of claim 87, wherein the nucleic acid comprises an E1A gene.

89. (New) The complex of claim 77, wherein the lipid is a cationic lipid.

90. (New) The complex of claim 77, wherein the lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

91. (New) The complex of claim 77, wherein the polypeptide is from about 20 to about 100 amino acids in length.

92. (New) The complex of claim 77, wherein the complex further comprises a neutral phospholipid species.

93. (New) The complex of claim 87, wherein the ratio of the nucleic acid:lipid:polycationic polypeptide salt is about 1 µg/0.1 nmol/0.01 µg to about 1 µg/200 nmol/100 µg.

94. (New) The complex of claim 77, wherein the complex has a diameter of less than about 400 nm.

95. (New) The complex of claim 77, wherein the complex is shielded.

96. (New) The complex of claim 77, further comprising a lipophilic surfactant.

97. (New) The complex of claim 77, further comprising a compound comprising polyethylene glycol moieties.

98. (New) A method for producing a drug/lipid/polycationic polypeptide salt complex of claim 77, the method comprising combining the drug, the lipid, the polycationic polypeptide salt, and the targeting factor to form the complex.

99. (New) The method of claim 98, wherein the drug, lipid and polycationic polypeptide salt are mixed in a ratio of about 1 μg/0.1 nmol/0.01 μg to 1 μg/200 nmol/100 μg.

100. (New) The method of claim 98, wherein the lipid is a cationic lipid.

101. (New) The method of claim 100, wherein the cationic lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

102. (New) The ~~method of claim 98, wherein the drug~~ is a ~~nucleic acid~~.

103. (New) The method of claim 98, wherein the polycationic polypeptide salt is a protamine sulfate.

104. (New) A method for delivering drug to cells comprising contacting the cells with the complex of claim 77.

105. (New) The method of claim 104, wherein the cells are contacted with the complex *in vivo*, the method comprising administering the complex to an animal or human in an amount effective to deliver the drug into the cells of the animal or the human.

106. (New) The method of claim 105, wherein the drug comprises a nucleic acid, the lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol), and the polycationic polypeptide salt is a protamine sulfate.

107. (New) The complex of claim 77, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

108. (New) The complex of claim 77, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

109. (New) The complex of claim 77, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

110. (New) The complex of claim 81, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

111. (New) The complex of claim 81, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

112. (New) The complex of claim 81, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

113. (New) A method of administering a drug to a human or animal, the method comprising administering to the human or animal a drug/lipid/polycationic polypeptide salt complex comprising a drug, at least one lipid species, and at least one polycationic polypeptide salt, wherein the complex is administered intratumorally, intravenously, intratracheally, intraperitoneally or intramuscularly.

114. (New) The method of claim 113, wherein the complex is administered intraveneously.

115. (New) The method of claim 113, wherein the complex is administered as an aerosol or liquid solution.

116. (New) The method of claim 113, wherein the complex comprises a drug, at least one lipid species, and at least one polycationic polypeptide salt in a ratio such that the complex has a positive charge excess of lipid and polycationic polypeptide to drug.

117. (New) The method of claim 113, wherein the complex has a net neutral or net negative charge.

118. (New) The method of claim 113, wherein, in the polycationic polypeptide salt, arginine residues constitute at least about 30 % of the amino acid residues, and lysine residues constitute less than about 5 % of the amino acid residues of the polypeptide.

119. (New) A method of administering a nucleic acid to a human or animal, the method comprising administering to the human or animal a nucleic acid/lipid/polycationic

polypeptide complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide, wherein, in the polycationic polypeptide, arginine residues constitute about 65 to 75 % of the amino acid residues, and lysine residues constitute about 0 to 3% of the amino acid residues of the polypeptide;

wherein the complex is administered intratumorally, intravenously, intratracheally, intraperitoneally or intramuscularly.

120. (New) The method of claim 119, wherein the complex has a net positive charge.

121. (New) The method of claim 119, wherein the complex has a net neutral or net negative charge.

122. (New) The method of claim 113, wherein the polycationic polypeptide salt is a sulfate salt.

123. (New) The method of claim 113, wherein the polycationic polypeptide salt is a protamine sulfate.

124. (New) The method of claim 113, wherein the drug is a nucleic acid.

125. (New) The method of claim 124, wherein the nucleic acid comprises an E1A gene.

126. (New) The method of claim 113, wherein the lipid is a cationic lipid.

127. (New) The method of claim 113, wherein the lipid is 3ß[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

128. (New) The method of claim 113, wherein the polypeptide is from about 20 to about 100 amino acids in length.

129. (New) The method of claim 113, wherein the complex further comprises a neutral phospholipid species.

130. (New) The method of claim 113, wherein the complex has a diameter of less than about 400 nm.

131. (New) The method of claim 113, wherein the complex is shielded.

132. (New) The method of claim 113, wherein the complex further comprises a lipophilic surfactant.

133. (New) The method of claim 113, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

134. (New) The method of claim 113, wherein the drug, lipid and polycationic polypeptide salt are present in a ratio of about 1 μg/0.1 nmol/0.01 μg to 1 μg/200 nmol/100 μg.

135. (New) The method of claim 113, comprising administering the complex to an animal or human in an amount effective to deliver the drug into cells of the animal or the human.

136. (New) The method of claim 113, wherein the complex further comprises a targeting factor.